

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names, and; ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. Stephen J. Murphy, III
Mag. R. Steven Whalen

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW
BIOLOGICS, INC.'S OPPOSITION TO TRUTEK'S
SECOND MOTION FOR LEAVE TO AMEND**

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STATEMENT OF ISSUE PRESENTED

1. Whether this Court should deny Trutek's second Motion for Leave to Amend the Complaint to add a count of willful infringement, where the previous motion to amend was denied, the currently proposed amendment is futile, fact discovery is closed, Plaintiff has failed to comply with every discovery deadline, and a ruling on Defendant's Motion to Exclude Damages is forthcoming.

Defendant/Counter-Plaintiff BlueWillow Biologics, Inc.'s Answer: **Yes.**

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I. INTRODUCTION

Defendant BlueWillow Biologics, Inc. (“BlueWillow”) continues to reiterate, this is a classic nuisance patent lawsuit in which Plaintiff Trutek Corp. (“Trutek”) is seeking to extort a settlement based on the cost of defending against a patent infringement suit. Despite Trutek’s copious protestations, Trutek *continues* to miss nearly every discovery deadline. In an attempt to further delay, Trutek now wishes to start its damages case all over again—attempting to assert, for the first time, a new claim of willful infringement.¹ Trutek’s Motion should be denied in its entirety.

Discovery has closed and there is a Court Order declaring that, to avoid prejudice, discovery would not be extended without BlueWillow’s consent. This Court has already denied Trutek’s previous motion to amend. The deadline for fact discovery has long passed and the close of expert discovery is in less than two weeks. Trutek’s Motion consists entirely of bare recitations and conclusory assertions without citation to applicable law on the issues of willful infringement or enhanced damages, let alone any reference to this case’s history or any

¹ Nevertheless, Trutek’s Motion will be mooted if the Court grants BlueWillow’s motion to exclude Trutek’s damages theories. (*See* ECF No. 43, BlueWillow’s Motion to Exclude Damages-Related Theories or Evidence.) In the abstract, the Court may award up to three times the “amount found or assessed” in a patent infringement case. 35 U.S.C. § 284. However, if there are no damages, the availability of enhanced damages logically does not exist.

meaningful justification for its repeated delays. In short, this is another haphazard attempt to raise litigation costs and delay final resolution.

The undeniable reality is that Trutek seeks to amend based on information that easily could have been in its possession immediately after it filed the original Complaint in February 2021. The allegations made by Trutek in its Complaint demonstrate without a doubt that it could have determined whether the accused product was sold in the United States after the Complaint was filed. (*See* ECF No. 1 at ¶ 16 (“[O]n June 23, 2020, TRUTEK personnel purchased the NANOBIO product from Amazon.com” and on “January 14, 2021, TRUTEK personnel purchased a NANOBIO product from CVS”), ¶ 18 (“On January 31, 2021, Keith Altman . . . ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online from Amazon.com”).) If Trutek wanted to know if the accused product was still on sale after the complaint was filed, all it had to do was check Amazon.com or visit a CVS, as it had done repeatedly in the past, to see if the product was still available for purchase.

Ignoring that fact, the only justification Trutek provides for its delay is based on financial records it obtained in June—which Trutek received out of BlueWillow’s gratuitous disclosure. Trutek’s only “substantive” argument in defense of its delay is the bare assertion that BlueWillow did not disclose this information until after the close of fact discovery. However, it is Trutek’s

responsibility to seek discovery within the time period proscribed by the Court. Trutek also does not explain why it waited until now to file a Motion to Amend based on evidence disclosed in June. (*See* ECF No. 46-1, June 4, 2022 Email.)

Finally, despite Trutek's claim to the contrary, Trutek's proposed amended complaint would be subject to a motion to dismiss under Fed. R. Civ. P. 12(b)(6), and the proposed amendment is futile under applicable legal standards. In short, the Court should once again deny Trutek's motion for leave.

II. BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines for challenging respiratory infections, sexually transmitted diseases, and food allergies.

On **February 10, 2021**, Trutek filed suit alleging one count of patent infringement of United States Patent No. 8,163,802 ("the '802 Patent") against BlueWillow with respect to a single product, NanoBio[®] Protect. (ECF No. 9, Counterclaim, ¶ 6; ECF No. 1, Complaint). The '802 Patent is attached as Exhibit 6 to the Complaint. (ECF No. 1-6.) Trutek's Complaint alleges that BlueWillow's NanoBio[®] Protect directly infringes "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio[®] Protect] products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide." (ECF No. 9, Counterclaim, ¶ 9; ECF No. 1, Complaint, ¶ 30.) Trutek's

Complaint also alleges that Trutek personnel and Trutek's counsel were able to purchase the accused product directly from retail locations such as Amazon and CVS. (ECF No. 1, Complaint ¶¶ 16, 18.)

On **May 19, 2021**, BlueWillow filed its responsive pleading, including its Counterclaims. (ECF No. 9.) Since that time, Trutek has not prosecuted its case.

On **November 03, 2021**, the Court entered a scheduling order stating that fact discovery shall be completed by April 1, 2022. Yet, Trutek failed to issue a single discovery request before this deadline.

On **February 18, 2022**, BlueWillow issued its First Set of Document Requests and Interrogatories. On **March 2, 2022**, BlueWillow served its Second Set of Requests for Production.

On **March 18, 2022**, Trutek filed a motion to extend the scheduling order by 45 days. (ECF No. 24.) On **March 23, 2022**, the Court granted the motion, extending fact discovery to May 16, 2022, and witness disclosures to May 11, 2022. The Court "warn[ed] Plaintiff that there will be no further extensions to these deadlines unless the parties agree to extend a deadline." (ECF No. 26, PageID 269.)

Notably, while Trutek's motion did not request, and the resulting Order did not grant, an extension on Trutek's time to respond to discovery requests, BlueWillow (in a show of good faith) operated as if the Court's Order had made

such a declaration. Nevertheless, Trutek failed to timely respond to BlueWillow's First Set of Requests for Production and Interrogatories even assuming a 45-day extension. Trutek only responded after being notified that its objections had been waived. (ECF No. 30-5, May 11, 2022 Email from L. Peterson to K. Altman and S. Kremen.)

Trutek subsequently failed to timely respond to BlueWillow's Second Set of Requests for Production—which was due on May 16, 2022 (the last day for the close of discovery).² As of the date of this Opposition, BlueWillow has not received such responses.

Trutek also failed to meet the deadline for witness list disclosures. (*See* ECF No. 29 (two days late).)

On **May 11, 2022**, Trutek issued its first set of document requests to BlueWillow, only 5 days before the close of the discovery deadline (as amended). Although there is only one accused product in this case—NanoBio[®] Protect—Trutek's requests were extensive (numbering 53 total requests), and were almost entirely directed to the non-accused Developmental Vaccine Candidates. (ECF No. 30-2.)

² Assuming the generous interpretation that Trutek received a 45-day extension as to discovery requests.

On the **same day**, Trutek filed a Motion seeking leave to amend the Complaint. (ECF No. 28.) On **June 2, 2022**, the Court denied Trutek's Motion to amend. (ECF No. 32.)

On **August 17, 2022**, BlueWillow served its Third Set of Requests for Production directed at expert discovery. Thus, Trutek's responses were due September 16, 2022. Again, Trutek did not provide timely responses—and to this day, has still not provided written objections or responses. It was not until **October 22, 2022** (not even one business day prior to the scheduled depositions of Trutek's experts, which began on October 24, 2022), that Trutek produced *some* of the information responsive to BlueWillow's Requests.

On **September 26, 2022**, BlueWillow filed a Motion in Limine to Exclude Damages Related Theories and Evidence.

On **October 5, 2022**, Trutek filed this second Motion for Leave to Amend the Complaint claiming that, based on a document provided on June 4, 2022 (*See* ECF No. 46-1, June 4, 2022 Email), Trutek discovered a new theory of a willful infringement.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 15(a)(2) provides that a party may amend its pleading with the court's leave and that "the court should freely give leave when justice so requires." Denial of a motion to amend is appropriate, however,

where there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.” *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002).

IV. ARGUMENT

A. Trutek’s Motion Should be Denied for Undue Delay and Unfair Prejudice

Recognizing the risk of granting Trutek’s prior request to extend discovery, the Court stated, “[t]o minimize any prejudice that may result from extending discovery, the Court will warn Plaintiff that there will be no further extensions to these deadlines unless the parties agree to extend a deadline.” (ECF No. 26, PageID 269.) Trutek has once again waited to the final hour and seeks to delay final resolution of this case. Notably, Trutek’s request to add a willful infringement theory relates to “a fact-intensive issue that requires consideration of the totality of the circumstances” *Balboa Instruments, Inc. v. Gecko Electronique*, No. SA CV 98–1053 AHS, 2002 WL 34453502, at *1 (C.D. Cal. Mar. 20, 2002) (citing *American Medical Sys., Inc. v. Medical Eng’g Corp.*, 6 F.3d 1523, 1530 (Fed. Cir. 1993)).

The Sixth Circuit has explained that where a party seeks leave to amend after the close of discovery there is “an increased burden is on the movant at this late stage in the litigation to show justification for the failure to move earlier.”

Duggins v. Steak ‘N Shake, Inc., 195 F.3d 828, 834 (6th Cir. 1999). In *Bridgeport Music, Inc. v. Dimension Films*, 410 F.3d 792, 806–807 (6th Cir. 2005), the Sixth Circuit affirmed a district court’s denial of leave to amend with only a few weeks of discovery remaining. *See also R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 440–441 (6th Cir. 2005) (affirming denial of leave where discovery was complete). In this case, the deadline for fact discovery has long passed and there is less than two weeks until expert discovery is closed.

Trutek has failed to give a plausible explanation as to why it only now seeks to amend the Complaint to add contentions about alleged willful infringement. *See Scott v. Hemlock Semiconductor Corp.*, No. 06-14903-BC, 2007 WL 2649360, at *3 (E.D. Mich. Sept. 10, 2007) (denying motion to amend where no explanation was given for why a claim was not brought in the previously filed complaint). This suit was filed in February 2021, and Trutek’s 18-month delay is inexcusable. *See Springs v. Mayer Brown LLP*, No. 11–CV–13518, 2013 WL 656494, at *1 (E.D. Mich. Feb. 22, 2013) (describing 14-month delay as “inexcusable”).

Trutek asserts its Motion was brought because “BlueWillow Biologics, Inc., did not produce financial records until after the close of discovery.” (ECF No. 44, PageID 804.) There are several problems with this line of reasoning. First, it was Trutek’s responsibility to timely serve document requests and prosecute its case prior to the close of fact discovery. *See Dorchen/Martin Associates, Inc. v. Book of*

Cheboygan, Inc., No. 11–10561, 2013 WL 593953, at *1–2 (E.D. Mich. Feb. 15, 2013) (denying leave to amend where plaintiff waited nearly four months after the close of discovery to request leave) (noting there were numerous ways that plaintiff could have discovered the “new” information prior to the close of discovery).

Second, even outside of discovery, any allegations of willful infringement based on post-complaint sales could have been discovered by purchasing the products immediately after filing the Complaint. Indeed, Trutek’s Complaint admits that “Trutek personnel” and Trutek’s counsel, Keith Altman, were not only aware of this fact, but had already purchased the accused product from Amazon and CVS on multiple occasions. (ECF No. 1, Complaint ¶¶ 16, 18; ECF No. 1-5, Declaration of Keith Altman, ¶ 2 (“On January 31, 2021, I ordered one unit of NanoBio Nasal Antiseptic online from Amazon.com using my computer, which is located in the State of Michigan”).) This fact is of particular relevance when assessing Trutek’s assertion that it sought leave to amend “[u]pon learning that BlueWillow continued to market, distribute, and sell the Nanobio product after Trutek served its original Complaint.” (ECF No. 44, Second Motion for Leave, PageID 807.) Trutek has not provided any justification for why it could not have discovered this information earlier, let alone immediately after filing the complaint. Nor has Trutek argued that it needed to know the amount of sales, as

opposed to the mere existence of post-complaint sales, in order to assess whether it could assert a claim for willful infringement. It is clear that the only reason why this Motion was brought is in response to BlueWillow's Motion in Limine.

Third, dispositive motions are due on December 12, 2022, in approximately a month. (ECF No. 26, PageID 268.) This is also sufficient to show prejudice. *See J.S.T. Corp. v. Robert Bosch LLC*, 15-13842, 2019 WL 2017177, at *6 (E.D. Mich. Apr. 23, 2019) (imminent deadline for dispositive motions shows prejudice) (citing *Miller v. Admin. Office of Courts*, 448 F.3d 887, 898 (6th Cir. 2006)).

Fourth, Trutek offers no explanation for why it waited five months after obtaining the financial documents in question to file this instant motion. (*Cf.* ECF No. 46-1, June 4, 2022 Email.) *See Odish v. Peregrine Semiconductor, Inc.*, No. 2:13-CV-14026, 2014 WL 12659591, at *1 (E.D. Mich. Nov. 17, 2014) (rejecting vague assertion that the complaint seeks to “address newly discovered evidence”). Waiting many months to file for leave to amend is also sufficient to show prejudice. *Duggins*, 195 F.3d at 834 (“The plaintiff was obviously aware of the basis of the claim for many months”) Notably, Trutek has even failed to put the financial records in the record. In order to do so, Trutek should have, but did not cooperate in the execution of a protective order and did not properly file a motion to seal. (*Cf.* ECF 46-1, June 4, 2022 Email.)

BlueWillow will be unduly prejudiced if Trutek's motion to amend is granted. From the outset, it has been clear that the amount in controversy does not justify the expense or use of judicial resources to litigate Trutek's claims of infringement directed to NanoBio Protect[®]. Fact discovery has closed and expert discovery is set to close in less than two weeks. Contrary to Trutek's assertion, the proposed amendment does not "merely conform[] the Complaint to the evidence" or "only affect[] the statutory calculation of damages." (ECF No. 44, Second Motion for Leave, PageID 807.) If Trutek is permitted to assert willful infringement (and by extension, seek enhanced damages), BlueWillow will need to defend against those new claims, which relate to "a fact-intensive issue that requires consideration of the totality of the circumstances" *Balboa Instruments*, 2002 WL 34453502, at *1 (citing *American Medical Systems*, 6 F.3d at 1530); *see also Read Corp. v. Portec, Inc.*, 970 F.2d 816, 827–28 (Fed. Cir. 1992) (describing multiple factors to be considered by district court when exercising discretion to award enhanced damages upon a finding of willful infringement).

BlueWillow is entitled to finality at some point in this case.

B. Trutek's Motion Should be Denied for Futility

Trutek's proposed amended complaint to add a count of willful infringement is futile as the allegations are improperly conclusory and speculative and fail to conform to applicable pleading standards and the underlying law. *See Doe v. Mich.*

State Uni., 989 F.3d 418, 424 (6th Cir. 2021) (an amendment is futile when it cannot withstand a motion to dismiss). Notably, Trutek does not even state in its Motion the applicable legal standards for willful infringement and enhanced damages.

To survive a motion to dismiss, Trutek’s proposed complaint must plead “enough facts to state a claim to relief that is plausible on its face,” which turns on providing “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To establish willful infringement, the patentee must demonstrate both knowledge of the patent and knowledge of the infringement. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016); *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987–88 (Fed. Cir. 2021) (“To establish willfulness, the patentee must show that the accused infringer had a specific intent to infringe at the time of the challenged conduct.”). Infringement alone does not rise to the level of willful infringement, it must be deliberate or intentional. *Eko Brands, LLC v. Adrian Rivera Maynez Enters.*, 946 F.3d 1367, 1379 (Fed. Cir. 2020).

“Although willfulness is a component of enhancement, ‘an award of enhanced damages does not necessarily flow from a willfulness finding.’” *SRI Int’l, Inc. v. Cisco Sys.*, 14 F.4d 1323, 1330 (Fed. Cir. 2021) (quoting *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1382 (Fed. Cir. 2017)). Rather, the

decision of whether to award enhanced damages (and by how much) remains within the discretion of the District Court. *See id.* (“Discretion remains with the district court to determine whether the conduct is sufficiently egregious to warrant enhanced damages.”). “The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or – indeed – characteristic of a pirate.” *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 103–04 (2016). Relevant factors include “whether the infringer deliberately copied the ideas or design of another,” the “infringer’s behavior as a party to the litigation,” the infringer’s “size and financial condition,” the “closeness of the case,” “remedial action by the defendant,” the defendant’s “motivation for harm,” and “whether defendant attempted to conceal its misconduct.” *Read*, 970 F.2d at 827–28.

Trutek’s allegations directed to willful infringement and enhanced damages are improperly conclusory and speculative. Generally, courts construe a complaint in the light most favorable to the plaintiff and accept all well-pleaded factual allegations as true. *Ashcroft*, 556 at 678–79. However, the court “does not apply this presumption of truth to conclusory or legal assertions.” *Binno v. American Bar Association*, 826 F.3d 338, 345–46 (6th Cir. 2016). Claims of willful infringement are appropriate to consider in a motion to dismiss. *Mich. Motor Techs. LLC v. Volkswagen Aktiengesellschaft*, 472 F. Supp. 3d 377, 384–85 (E.D. Mich. 2020)

(granting motion to dismiss where allegations were “not sufficient to allege willful infringement” and noting that merely pleading awareness of the patent and “nothing else . . . is not enough to sustain a willful infringement claim for enhanced damages”).

For example, Trutek alleges that BlueWillow received notice of Trutek’s allegations of infringement when the original complaint was filed and that it “continued to market, distribute, and sell NANOBIO products for approximately months after learning that the NANOBIO products infringed on claims 1, 2, 6 and 7 of the ’802 patent.” (ECF No. 44-1, Proposed Amended Complaint, ¶¶ 30, 32.) These conclusory allegations, based on Trutek’s as-yet unproven allegations of infringement as stated in the Complaint, fall well short of stating a plausible claim that “the accused infringer had a specific intent to infringe at the time of the challenged conduct.” *Bayer Healthcare*, 989 F.3d at 987–88.

Likewise, with respect to enhanced damages, the proposed amended complaint provides only a single conclusory allegation that BlueWillow’s financial records “establish by a preponderance of the evidence that enhanced damages are appropriate.” (ECF No. 44-1, Proposed Amended Complaint. ¶ 34.) Noticeably absent are any well-pled factual allegations that would support a reasonable inference that BlueWillow’s behavior was “willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or – indeed – characteristic of a pirate.”

Halo Electronics, 579 U.S. at 103–04. For all of the foregoing reasons, granting Trutek’s motion to amend would be futile as the proposed amended complaint would not survive a motion to dismiss.

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court deny Trutek’s Second Motion for Leave to Amend in its entirety.

Dated: November 2, 2022

Respectfully submitted,

FOLEY & LARDNER LLP

/s/ Alan J. Gocha

Nicholas J. Ellis (P73174)
Alan J. Gocha (P80972)
500 Woodward Avenue, Suite 2700
Detroit, MI 48226-3489
Telephone: 313.234.7100
Facsimile: 313.234.2800

Liane M. Peterson
3000 K Street NW, Suite 600
Washington, DC 20007
Telephone: 202.672.5300
Facsimile: 202.672.5399

*Attorneys for BlueWillow
Biologics, Inc.*

CERTIFICATE OF ELECTRONIC SERVICE

I hereby certify that on November 2, 2022, I electronically filed the foregoing document with the Clerk of the Court for the Eastern District of Michigan using the ECF System, which will send electronic notice to all participants.

/s/ Alan J. Gocha

Alan J. Gocha (P80972)

FOLEY & LARDNER LLP

500 Woodward Avenue, Suite 2700

Detroit, MI 48226-3489

Telephone: 313.234.7100

Facsimile: 313.234.2800